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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/043,639

01/09/2002

Patricia Sarcabal

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6528

7590

04/20/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,639	SARCABAL ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-51, 53-67 and 82-84 is/are pending in the application.
- 4a) Of the above claim(s) 33-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50, 51, 53-67 and 82-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 33-50, 51, 53-67 and 82-84 are pending in the instant application. Claims 33-49 have been previously withdrawn from consideration.
2. Claims 50, 51, 53-67 and 82-84 are under consideration in this Office Action.
3. The rejection of claim 64 under 35 USC 101 as being directed to non-statutory subject matter has been withdrawn in view of applicants' amendment to the claim filed on 01/27/2006.
4. The rejection of claims 50, 51, 57, 61-64, and 66 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' amendment to the claims filed on 01/27/2006.
5. The rejection of claim 65 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of applicants' statement in the amendment filed on 01/27/2006, where applicants state that all restrictions upon the availability to the public for the recited *E.coli* filed at the NCCM under the access No. I-2243 would be removed upon granting of a patent to the instant application.
6. The rejection of claims 50, 51, 53-63, 65-67 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of applicants' amendment to the claims and arguments filed on 01/27/2006.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 50, 51, and 53-67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
In each of claims 50 and 67, the phrase "with a complementary sequence" renders the

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claim vague and indefinite. It is not clear if applicants are actually referring to the full complement of SEQ ID NO: 1 or SEQ ID NO: 2. Claims 51 and 53-66 which depend from claim 50 are also rejected because they do not correct the defect of claim 50.

Amending the claims to recite the phrase "or the full complement of SEQ ID NO: 1 or SEQ ID NO: 2" or the phrase "or the full complement thereof" may overcome the rejection.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 64 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell transformed with vector comprising a recombinant nucleic acid comprising a polynucleotide region comprising at least 90% nucleotide identity to SEQ ID NO:1 or SEQ ID NO: 2 and coding for at least one subunit of a glycerol dehydratase; does not reasonably provide enablement for host cells within a multicellular organism that have been transformed with the vector of claim 61. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claim is so broad as to encompass host cells transformed with the recited polynucleotides, including cells in *in vitro* culture as well as cells within any multicellular organism. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of host cells broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods for successfully transforming cells within complex multicellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within one multicellular organism are unlikely to be applicable to transformation of other types of multicellular organisms as multicellular organisms vary widely. However, in this case the disclosure is limited to only host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multicellular organism for the production of the recited glycerol dehydratase.

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The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, expression of polynucleotides in a particular host cell and having the desired biological characteristics is unpredictable the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is suggested that applicants limit the claims to “an isolated recombinant host cell “.

11. Claims 82-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process using an expression vector comprising a recombinant nucleic acid encoding a glycerol dehydrates having at least 90% amino acid identity with SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first polypeptide that has at least 90% amino acid identity to SEQ ID NO: 6 and a second polypeptide that has at least 90% amino acid identity to SEQ ID NO: 7, or a recombinant nucleic acid that has at least 90% nucleotide identity to SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising an amino acid sequence of at least 90% amino acid identity to SEQ ID NO: 8; does not reasonably provide enablement for the full scope of the recited method encompassing any expression vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any process comprising preparation of any expression vector to be used in the production of the recited glycerol dehydratase. The specification provides guidance and examples for making a recombinant nucleic acid encoding a glycerol dehydrates having the amino acid sequence of SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first polypeptide that has the amino acid sequence of SEQ ID NO: 6 and a second polypeptide that has the amino acid sequence of SEQ ID NO: 7, and a recombinant nucleic acid comprising SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising the amino acid sequence SEQ ID NO: 8, where the specification discloses nucleotide sequences of SEQ ID NOs: 1-5.

However, the specification does not provide prediction, guidance, and working examples using any expression vector to be used in the recited method. Thus, an undue amount of experimentation must be preformed to search, screen, and make any expression vector that can be

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used in the recited method. Searching and screening for the claimed invention is not guidance for making the invention. Furthermore, searching and screening for the claimed invention is outside the realm of routine experimentation.

The examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequences of the recombinant nucleic acids that can be cloned into the recited vector and used in the recited method to make the claimed glycerol dehydratase. Without such guidance, the amount of experimentation left to those skilled in the art to make the invention is undue.

Amending the claims to recite an expression vector comprising a recombinant nucleic acid encoding a glycerol dehydratase having at least 90% amino acid identity with SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first polypeptide that has at least 90% amino acid identity to SEQ ID NO: 6 and a second polypeptide that has at least 90% amino acid identity to SEQ ID NO: 7, or a recombinant nucleic acid that has at least 90% nucleotide identity to SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising an amino acid sequence of at least 90% amino acid identity to SEQ ID NO: 8 may overcome the rejection.

Conclusion


12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

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TEKCHAND SAIDHA
PRIMARY EXAMINER